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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

BANSAL, G

ART UNIT	PAPER NUMBER
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1642

9

DATE MAILED:

01/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/194,164

Applicant(s)

Dan et al

Examiner

Geetha Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/30/00
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-50 is/are pending in the application.
- Of the above claim(s) 1-25, 39-50 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 26-38 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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### DETAILED ACTION

1. Applicant's election without traverse of Group II (claims 26-38) in Paper No. 8 is acknowledged.

#### *Claim Rejections - 35 U.S.C. § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26, 33-35, 37-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are drawn to a substantially isolated polynucleotide sequence that encodes an antigen binding fragment of an antibody which antibody specifically recognizes the antigen recognized by the antibody whose Hv and Lv regions are depicted by SEQ ID Nos 2 and 5. Further claims are drawn to the pharmaceutical compositions thereof, to cloning and expression vectors containing said polynucleotide, and to polynucleotides that are at least 20 nucleotides in length and hybridize to sequences consisting of SEQ ID No 4 or 6.

The specification teaches the identification of a human Mab H11 whose Hv and Lv are depicted by the SEQ ID Nos 2 and 5. The specification also discloses the reactivity pattern of Mab H11 by an immunofluorescence assay, and disclose the antibody as binding to cell surface antigens present on certain cancer cells and not to normal cells. The specification does not teach the nature of the C antigen -its chemical or molecular weight, nor provide any guidance as to how to identify and isolate the antigen so that antibodies to it can be made or identified. There is no guidance provided as to how to characterize the C antigen nor determine if it is immunogenic by itself so as to elicit the production of antibodies. The working example disclosed demonstrated

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reactivity to cell surfaces of cancer cells and not to normal cells. There is no direction provided as to how to obtain other monoclonal antibodies since there is no written description of what the antigen is. Thus, in the absence of a knowledge of the C antigen, one of skill in the art would be forced into undue experimentation to prepare monoclonal antibodies to the C antigen that is recognized by the claimed antibody fragment.

4. Claim 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are drawn to a pharmaceutical composition comprising the polynucleotide of claim 26. The specification teaches the identification of a human Mab H11 whose Hv and Lv are depicted by the SEQ ID Nos 2 and 5. The specification also discloses the reactivity pattern of Mab H11 by an immunofluorescence assay, and disclose the antibody as binding to cell surface antigens present on certain cancer cells and not to normal cells. The specification does not teach the nature of the C antigen -nor its usefulness in a therapeutic setting. Thus the specification does not provide any guidance as to the use of a polynucleotide sequence encoding an antibody that recognizes C antigen which is immunogenic nor does it provide any guidance or working examples as to how it is contemplated to be useful as a pharmaceutical composition. One of skill in the art would be forced into undue experimentation to produce such a nucleic acid molecule specially when there is no teaching as to the utility of the C antigen such that the functional epitopes with therapeutic benefits can be assessed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 28, 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 32 is drawn to a nucleic acid molecule comprising a region of 20 nucleotides that forms a duplex with SEQ ID No 4 or 6, whereas claim 28, 29 are drawn to whole encoding sequences that is contained within SEQ ID Nos 1 and 4.

B. Claims 28 and 29 lack antecedent basis in the claims with respect to the recitation of "encoding sequence".

C. Claim 32, (28, 29, 30) and 36 are ambiguous in that the metes and bound of "stable duplex" is not clear.

7. Claims are free of the prior art searched.

8. The PTO-1449 has been entered. However, the Examiner is unable to obtain the parent case and therefore all of the references could not be reviewed. A signed copy of the PTO-1449 will be sent with the next office action.

9. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and

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alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell, can be reached on (703) 308-4310.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 12, 2001

  
**GEETHA P. BANSAL**  
**PRIMARY EXAMINER**